



UNITED STATES PATENT AND TRADEMARK OFFICE

MAR 5 2001

Commissioner for Patents  
United States Patent and Trademark Office  
Washington, D.C. 20231  
www.uspto.gov

Mary-Ellen M. Devlin  
BOEHRINGER INGELHEIM  
PHARMACEUTICALS INC.  
900 Ridgebury Rd., P.O. Box 368  
Ridgefield CT 06877-0368

Re: Patent Term Extension  
Application for  
U.S. Patent No. 5,216,167, Reissue  
Patent No. 37,035

Dear Ms. Devlin:

A certificate under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 5,216,167, Reissue Patent No. 37,035 for a period of 921 days. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products).

Telephone inquiries regarding this communication should be directed to the undersigned at (703)306-3159.

Karin Tyson  
Senior Legal Advisor  
Office of Patent Legal Administration  
Office of the Assistant Commissioner for Patent Examination Policy

cc: David T. Read  
Acting Director Regulatory Policy Staff, CDER  
Food and Drug Administration  
1451 Rockville Pike, HFD-7  
Rockville, MD 20852

Re: PRANDIN™ (repaglinide)  
FDA Docket No. 98E-0616

# UNITED STATES PATENT AND TRADEMARK OFFICE

## CERTIFICATE EXTENDING PATENT TERM UNDER 35 U.S.C. § 156

REISSUE PATENT NO. : RE 37,035  
ISSUED : January 30, 2001  
REISSUE OF U.S. PATENT NO. : 5,216,167  
ISSUED : June 1, 1993  
INVENTORS : Wolfgang Grell et al.  
PATENT OWNER : Dr. Karl Thomae GmbH  
PRODUCT : PRANDIN™ (repaglinide)

This is to certify that an application under 35 U.S.C. § 156 has been filed in the United States Patent and Trademark Office, requesting extension of the term of U.S. Patent No. 5,216,167, now U.S. Reissue Patent No. RE 37,035, based upon the regulatory review of the product PRANDIN™ (repaglinide) by the Food and Drug Administration. Since it appears that the requirements of the law have been met, this certificate extends the term of the patent for the period of

921 days

from September 5, 2006, the original expiration date of the reissue patent, subject to the provisions of 35 U.S.C. § 41(b), with all rights pertaining thereto as provided by 35 U.S.C. § 156(b).



I have caused the seal of the United States Patent and Trademark Office to be affixed this 8th day of February 2001.

*Nicholas P. Godici*

Nicholas P. Godici

Acting Under Secretary of Commerce for Intellectual Property and  
Acting Director of the United States Patent and Trademark Office